REMARKS

Reconsideration and reexamination of the subject application are respectfully requested in light of the foregoing amendments and following remarks.

1. Status of the Claims

Claims 1-20 stand pending. Claims 1-20 stand rejected. By entry of the present amendment, claims 1-4 and 8-20 are canceled, and new claims 21-30 are added.

2. Support for the Amendments

The amendments are supported throughout the specification as filed. Amendments to claims 5 and 23 are supported in the specification at page 7, lines 10-12 and 15-17, for example. Claim 24 is supported at page 7, lines 18-20, for example. Claims 27 and 30 are supported at least at page 7, lines 27-31, and page 9, lines 26-32 (obesity as a lifestyle related disease). An analogue of sesamin and episesamin comprising a dioxabicyclo[3.3.0]octane moiety is supported at least at page 10, lines 9-27, for example.

3. Acknowledgement of Information Disclosure Statement

Applicants acknowledge with appreciation the entry of the Information Disclosure Statement filed September 25, 2006.

4. Acknowledgement of Certified Priority Documents

Applicants note with appreciation the acknowledgement of receipt of the certified priority document.

5. Rejection under 35 U.S.C. § 101

Claims 13-15 are rejected under 35 U.S.C. § 101 because the recitation of a use, without setting forth any steps involved in the process, allegedly results in an improper definition of a process. The rejection is moot in view of the cancellation of claims 13-15.

6. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-18 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office alleges that

"[T]here is no clarity as to which compounds are encompassed by the term 'analogue.' Additionally, there is no distinction or limitation in the instant claims to determine a practicing analogue of sesamin or episesamin in comparison to a general core moiety of sesamin or episesamin." Applicants traverse the rejection as it applies to the amended claims.

To satisfy the written description requirement, the applicant must convey to the skilled artisan that, as of the filing date sought, the applicant was in possession of the invention. *See Falkner v. Inglis*, 448 F.3d 1357, 1365, 79 U.S.P.Q.2d 1001, 1007 (Fed. Cir. 2006). The description needed to satisfy the requirements of 35 U.S.C. § 112 varies with the nature and scope of the invention at issue and with the scientific and technologic knowledge already in existence. *See Capon v. Eshhar*, 418 F.3d 1349, 1358, 76 U.S.P.Q.2d 1078, 1084-85 (Fed. Cir. 2005).

The presently recited analogues of sesamin or episesamin comprise a dioxabicyclo[3.3.0]octane moiety. Extensive scientific and technologic knowledge already existed regarding sesamin or episesamin analogues comprising the dioxabicyclo[3.3.0]octane core moiety. These analogues include those listed in the specification at page 10, lines 9-27: the dioxabicyclo[3.3.0]octane derivatives described in Japanese Unexamined Patent Publication HEI No. 4-9331, sesaminol, episesaminol, sesamolin, 2-(3,4-methylenedioxyphenyl)-6-(3-methoxy-4-hydroxyphenyl)-3,7-dioxabicyc- lo[3.3.0]octane, 2,6-bis(3-methoxy-4-hydroxyphenyl)-3,7-dioxabicyclo[3.3.0]octane, 2-(3,4-methylenedioxyphenyl)-6-(3-methoxy-4-hydroxyphenoxy)-3,7-dioxabicy- clo[3.3.0]octane, 2-(3,4-methylenedioxyphenyl)-6-(3,4-dihydroxyphenyl)-3,7-dioxabicyclo[3.3.0]octane, 2-(3-methoxy-4-hydroxyphenyl)-6-(3,4-dihydroxyphenyl)-3,7-dioxa- bicyclo[3.3.0]octane and 2,6-bis(3,4-dihydroxyphenyl)-3,7-dioxabicyclo[3.3.0]octane, glucosides of sesamin, and sesamin metabolites. In light of this knowledge in the art, the present claims provide adequate clarity regarding the compounds embraced by the term "analogue."

Further, the presently recited analogues possess a biological activity, such as augmenting adiponectin production in an individual. The artisan would expect the recited analogues to possess the same biological activity as sesamin or episesamin, because they share the common dioxabicyclo[3.3.0]octane core moiety. Accordingly, the specification adequately conveys to the skilled artisan that, as of the filing date, Applicant was in possession of the claimed invention. Thus, the rejection may be withdrawn.

7. **Rejection under 35 U.S.C. § 112, Second Paragraph**

Claims 13-20 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language at issue does not occur in the amended claims, and the rejection accordingly is moot.

8. **Rejection under 35 U.S.C. § 103(a)**

(a) Claims 1-20 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,397,778 ("Forse") and JP 06227977A ("Sumio") in view of JP 11246427 A ("Keizo") and JP 908268887A ("Kengo"). To clarify the record, computer translations of Sumio, Keizo, and Kengo are provided as **Exhibits 1, 2, and 3**, respectively. Applicants traverse the rejection.

Forse

Forse discloses formulations containing a lignan from the sesamin family that may be used to treat infection or inflammation. Forse, Abstract; col. 2, lines 27-28; col. 3, lines 1-3 and 11-13; col. 4, lines 21-23. Forse thus suggests administering lignans to an individual suffering from infection or inflammation.

Sumio

Sumio discloses that sesamin may be useful for controlling active oxygen production, particularly OH radical production. *E.g.*, Sumio, ¶ 10. Sumio suggests the use of sesamin to treat individuals with ischemic reperfusion failure, liver inflammation, arteriosclerosis, shock, kidney disease, diabetes mellitus, cataracts, cancer, chronic dermatosis, allergic disease, epilepsy, drug intoxication, and Behcet's disease. *E.g.*, Sumio, ¶ 21.

Keizo

Keizo discloses using sesamin to promote activation of saccharometabolism and lipid metabolism. *E.g.*, Keizo, ¶¶ 5-6, 12. Keizo teaches that the effect of sesamin is synergistic with insulin. *E.g.*, Keizo, ¶ 15. Keizo suggests that the observed effect is related to promoting the differentiation of adipose cells to fat cells. *E.g.*, Keizo, ¶¶ 11-13, 17. Based on the observed activity of sesamin, Keizo suggests administering episesamin, or analogues thereof to an individual suffering from diabetes mellitus, hyperlipidemia, hypertension, or arteriosclerosis. *E.g.*, Keizo, ¶42.

Kengo

Kengo discloses a dioxabicyclo[3.3.0]octane derivative useful for suppressing the elevation of blood pressure. *E.g.*, Kengo, Abstract. Kengo suggests using the derivative to treat individuals with symptoms of hypertension. *E.g.*, Kengo, ¶ 22.

The combined references

The combined teachings of the cited art suggest administering sesamin, episesamin, or analogues to individuals suffering from particular indications. The combined teachings of the cited art, however, do not suggest administering sesamin, episesamin, analogues, or combinations thereof to an individual having an indication other than those enumerated above. Particularly, none of the cited art discloses or suggests a method comprising administering sesamin, episesamin, or an analogue thereof to augment adiponectin production, promote inducement of small adipocytes, or suppress accumulation of TNFα-producing enlarged adipocytes in an individual, as claimed. Thus, the combined disclosures of Forse, Sumio, Keizo, and Kengo would not have suggested the claimed invention to the artisan of ordinary skill at the time of the invention.

Undisclosed properties of sesamin, episesamin, or analogues thereof, even if inherently present in the prior art teachings, are irrelevant for the purpose of determining obviousness under 35 U.S.C. § 103. A rejection under 35 U.S.C. § 103 cannot be based solely on inherent properties of the prior art that the artisan of ordinary skill did not appreciate at the time of the invention. *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (holding that a retrospective view of inherency is no substitute for some teaching or suggestion in the art supporting an obviousness rejection); *In re Spormann*, 363 F.2d 444, 448 (C.C.P.A. 1966) ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."); *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977) (holding an obviousness rejection improper, where the prior art did not reveal the property that applicants had discovered); *see also In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989); *In re Grasselli*, 713 F.2d 731, 739 (Fed. Cir. 1983). For all the reasons above, the Office has not made a *prima facie* case of obviousness, and the rejection should be withdrawn.

(b) "For evidentiary purposes," the Office cites Jeng *et al.*, *Current Enzyme Inhibition* 1: 11-20 (2005) ("Jeng") and Jernas *et al.*, *FASEB J.* 20: 1540-42 (2006) ("Jernas"). Office Action, page 5. Jeng was published in January 2005, after the June 28, 2004 priority date claimed under 35 U.S.C. § 119(a) to JP 2004-189719 (*see* **Exhibit 4**). Jernas was published in 2006, after the International Filing Date, March 30, 2005. Accordingly, neither reference is prior art.

It is axiomatic that art must be available under some section of 35 U.S.C. § 102 before it can be used as evidence obviousness under 35 U.S.C. § 103. Neither reference, however, is prior art under 35 U.S.C. § 102. Thus, neither reference evidences that the claimed methods would have been "well-known to the skilled artisan" at the time of the invention, as the Office appears to allege at the top of page 6 of the Office Action. The Office's apparent use of Jeng and Jernas to establish what was known at the time of the invention is improper, and the Office is respectfully requested to clarify the record accordingly.

CONCLUSION

Should the Examiner have any questions or comments regarding Applicants' amendments or response, he is asked to contact Applicants' undersigned representative at (202) 842-8862. Please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully submitted,

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